IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

In re Namenda Direct Purchaser Antitrust Litigation THIS DOCUMENT RELATES TO: All Direct Purchaser Actions	Case No. 1:15-cv-07488-CM (JF)

FOREST'S OPPOSITION TO DIRECT PURCHASER PLAINTIFFS' MOTION FOR CLASS CERTIFICATION

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INTRODUCTION

Faced with undisputed proof that Forest settled the patent infringement actions against the first-filing generic manufacturers below the costs of litigation, Direct Purchaser Plaintiffs' ("DPPs") expert on class certification and damages, Dr. Lamb, confirmed that "[i]t's my understanding that . . . only the agreement between Forest and Mylan is challenged anticompetitive by the plaintiffs." Decl. of Michael E. Hamburger, Ex. 1 (Lamb Dep. 231:20-21). Similarly, DPPs' expert on reverse-payment issues, Professor Elhauge, is "offering no opinion on whether there was an overarching conspiracy between Forest and all of the generics." *Id.* Ex. 2 (Elhauge Dep. 39:16-19). None of DPPs' six other expert witnesses offers an opinion on the settlements with the other first-filing generics, and DPPs' Motion presents no evidence as to those agreements. The only remnant of DPPs' reverse-payment claim relates to Mylan.

As to DPPs' product-hopping claim, this Court has noted that the "injunction blunted much of the success of Forest's 'hard switch.'" *Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis plc*, No. 15-cv-7488, 2016 U.S. Dist. LEXIS 128349, at *30 (S.D.N.Y. Sept. 13, 2016) ("MTD Order"). This Court thus set forth the precise elements that DPPs must prove in order to show injury: (1) "patients switched to Namenda XR because of the announced withdrawal of Namenda IR"; (2) DPPs "were forced to pay for certain patients' memantine treatment at brand-name prices because the patients switched to Namenda XR *prior* to the entry of the injunction"; and (3) DPPs paid for these patients' use of "Namenda XR *after* generic entry," *i.e.*, these patients did not switch back to IR. *Id.* at *38-39 (emphases in original).

Rather than doing so, DPPs have artificially constructed an unprecedented and unfit proposed class based on two alternative impact/damages models. The first purports to estimate damages flowing from *both* the alleged reverse payment to Mylan *and* the product hop. Lamb

Rep. ¶ 130.[1] But none of the cases cited by DPPs certified a class of direct purchasers consisting of both reverse-payment and product-hopping claimants, and to the best of Forest's knowledge no court has ever certified such a class, likely because the conduct and injury flowing from a reverse payment would be irrelevant to a class member with only product-hopping claims, and vice versa. Moreover, the product-hopping claim here is unique in that the withdrawal was thwarted and Namenda IR always remained available. The second model addresses the product hop alone, and assumes that generic manufacturers entered just as they did in the actual world. Thus, the common thread in both of Dr. Lamb's models is product-hopping damages, and this is where DPPs' Motion is fundamentally flawed. Instead of complying with the Court's requirements, Dr. Lamb's methodology simply *assumes* impact and injury across the class:

> Q: . . . [S]o in that simple subtraction, your model *assumes* that all actual Namenda XR days of therapy above your but-for estimate consists of the anticompetitive hard switches at issue in this case?
>
> A: I think that's a fair way of characterizing it, sir.

Lamb Dep. 46:13-24 (emphasis added).

Although their reverse payment claim appears to have been narrowed, DPPs' Motion also attempts to *broaden* the class beyond that in DPPs' complaint by adding, for the first time, purchasers *of generic memantine* from *any generic manufacturer*. Courts refuse to sanction such expansions, particularly after fact discovery has closed. When DPPs are held to the class set forth in their complaint, and after the exclusion of other uninjured class members, DPPs cannot satisfy Rule 23(a)'s requirements of numerosity, typicality, or adequacy.

[1] Since filing Dr. Lamb's original report with their Motion (Litvin Decl., Ex. 3), DPPs have sent Forest an amended Lamb report. Forest has a number of concerns with the amended report, including alterations that materially impact Dr. Lamb's damages conclusions. In order to reserve its rights to seek to strike the amended report, Forest's citations herein are to the original report.

While the Court may end its inquiry there, DPPs' proposed class faces more insurmountable hurdles under Rule 23(b)(3). As noted above, Dr. Lamb makes no attempt to show whether the proposed class members' purchases of Namenda XR were for patients who switched to XR due to the February 14, 2014 announcement (the "February 2014 announcement") of Namenda IR's withdrawal, and who then stayed on Namenda XR after generic entry. As set forth below, other aspects of Dr. Lamb's methodologies rely on similar assumptions that result in significant errors. Neither of his damages models is capable of proving class-wide impact and damages.

For the reasons set forth below, the Court should deny DPPs' Motion.

BACKGROUND

I. NAMENDA IR AND NAMENDA XR

Alzheimer's is a progressive, degenerative disease of the brain for which there is no cure. All current therapies treat the symptoms of Alzheimer's but do not reverse its effects. Forest has been a leader in Alzheimer's treatments and research for more than a decade.

In 2000, Forest obtained an exclusive U.S. license for U.S. Patent No. 5,061,703, which covers all existing approved uses of Namenda. Forest then obtained FDA approval of Namenda IR, the first approved treatment for moderate to severe Alzheimer's disease, and launched Namenda IR on January 13, 2004. Hamburger Decl., Ex. 3 (press release). By the late 2000s, all other Alzheimer's treatments had released once-daily formulations. Hamburger Decl. Ex. 4 ¶ 25 (Report of Lona Fowdur, Ph.D. (Oct. 9, 2017)) ("Fowdur Rep."). Forest responded by spending $175 million developing once-daily Namenda XR, which was approved by the FDA in June 2010 and launched in June 2013. Fowdur Rep. ¶¶ 27, 61 n.154.

Namenda XR offers once-daily dosing, as well as flexible dosing that permits sprinkling XR's medicine over applesauce, all without an increase in side effects.[2] [redacted] Namenda XR's reduced pill burden is enormous, especially for persons aged 65 and over who on average take five medications per day. Hamburger Decl. Ex. 5 (Lah NYAG Hr'g 56:20-22); Fowdur Rep. ¶ 26 (citing literature).

II. LAWFUL PROMOTION AND MARKETING OF NAMENDA XR

The antitrust laws encourage both price and non-price competition. *See, e.g.*, *E.I. Du Pont de Nemours & Co. v. FTC*, 720 F.2d 128, 139-40 (2d. Cir. 1984). Brand companies compete on innovation, while generics compete with brands almost exclusively on price, because federal regulation allows them to free-ride on brand innovation. *Otsuka Pharm. Co. v. Price*, 869 F.3d 987, 990 (D.C. Cir. 2017). As part of XR's launch, Forest spent about [redacted] educating market participants about XR's benefits and its instructions for transitioning patients from IR to XR. Hamburger Decl. Ex. 6 (FRX-AT-01741562 at § 2.2); Fowdur Rep. ¶ 27.

Health plans, or payors, use formularies to influence the drugs doctors prescribe and patients take. Payors and pharmacy benefit managers ("PBMs") exercise significant leverage in driving drug sales. Lamb Rep. ¶¶ 17, 25 & n.35. Forest negotiated with top Medicare Part D national plans to obtain "preferred brand" formulary status for Namenda XR. Fowdur Rep. ¶ 27. The lower co-pay associated with "preferred brand" status lowers the price to patients and can be crucial to a new drug's success. Fowdur Rep. ¶ 20.

[2] Forest raises these points not to establish procompetitive reasons for withdrawing Namenda IR, but because they are relevant to the requirements for injury and causation set by the Court.

In order to promote Namenda XR, Forest discounted XR at least [redacted] below the wholesale acquisition cost of Namenda IR. Hamburger Decl. Ex. 7 (Decl. of William Meury ¶ 12). Additional XR discounts that Forest offered to health plans exceed [redacted] and were even higher than that for at least one Medicare Part D provider. *Id.* Ex. 8 (Devlin NYAG Dep. 120:10-18); *id.* Ex. 5 (Meury NYAG Hr'g 579:9-14, 580:20-581:5, 593:24-594:1). On average, managed care payors spent about [redacted] less for XR than for IR. *Id.* Ex. 9 (Meury NYAG Dep. 22:21-25, 23:3-7). All of these "soft-switch" efforts were lawful and do not give rise to an antitrust claim. MTD Order at *35-37.

III. MANAGED CARE DRIVES PATIENTS TO LOWER COST GENERICS

Once generic memantine entered the market in July 2015, patients that purchased solely on the basis of price had the option to switch from Namenda XR to generic IR, and were given strong incentives to do so by payors such as PBMs and insurers. Fowdur Rep. ¶¶ 20-21; Lamb Rep. ¶ 17. For example, some payors exclude certain brand drugs from their formularies. Fowdur Rep. ¶ 20. Others may require patients to use a cheaper drug before covering a more expensive brand. Fowdur Rep. ¶ 21. After generic IR entered, payors took such steps, creating incentives for patients to replace Namenda XR with generic IR. Fowdur Rep. ¶¶ 20-21.

IV. THE INJUNCTION PREVENTING WITHDRAWAL OF NAMENDA IR REMOVED ANY ANTICOMPETITIVE EFFECTS OF THE HARD SWITCH

On February 14, 2014, Forest announced plans to discontinue Namenda IR on August 15, 2014. In the spring of 2014, however, Forest discovered yield issues that limited its ability to ramp up XR production, and therefore announced on June 10, 2014 that IR would be available into the fall. Hamburger Decl. Ex. 10 (Stewart Decl. ¶¶ 8-11 (Oct. 21, 2014)). Before it resolved these yield issues, the State of New York sued Forest on September 15, 2014, and

sought to enjoin Forest from withdrawing or limiting access to IR. Fowdur Rep. ¶ 29. That month, Forest suspended its plans to withdraw IR and agreed to a "standstill" during the litigation, which was announced publicly in court and reported in the press. Fowdur Rep. ¶ 29.

On December 15, 2014, the court enjoined Forest from removing Namenda IR from the market or limiting its distribution until August 10, 2015, 30 days after generic IR would enter the market. Hamburger Decl. Ex. 11 (Settlement Agreement, Nov. 24, 2015, pp. 2-3) ("NYAG Settlement Agreement."). Pursuant to the injunction, in December 2014 Forest "informed healthcare providers, pharmacists, patients, caregivers, and health plans of the injunction and the continued availability of Namenda IR." *Id*. Forest fully complied with the injunction, and Namenda IR remains available to patients even today. *Id*.

Forest undertook an extensive campaign to notify the public about IR remaining on the market, sending over 900,000 communications to physicians and others. *See e.g.*, Hamburger Decl. Ex. 12 (Decl. of Julie Snyder, dated Oct. 6, 2017). Due to these efforts, the "[i]njunction was effective in protecting competition in the relevant market and permitting lower cost generic drugs to enter the market in July 2015 and subsequently." NYAG Settlement Agreement, p. 3; *see also* Mem. Decision & Order at 16 (May 23, 2017), ECF No. 253 ("Estoppel Order") (noting Forest had to "affirmatively undo the effects of its February 2014 announcement").

After the injunction and notifications that IR would remain available, XR adoption *increased*, rising from [redacted] by July 2015. Fowdur Rep. ¶ 106. [redacted] These strong levels of XR adoption among new users even after entry of generic memantine confirm that patients, doctors and caregivers selected XR because of its substantial benefits.

V. DPPS APPARENTLY NARROW THEIR REVERSE PAYMENT CLAIM

For over two years, DPPs alleged that Forest entered into anticompetitive reverse-payment settlements with eleven first-filing generic companies and that Forest conspired with them to delay generic entry through, among other things, contingent entry agreements. *See* First Am. Class Action Compl. ¶ 246 (Oct. 13, 2015), ECF No. 26 ("Complaint").[3] As noted above, however, their own experts have confirmed that DPPs are only challenging the settlement between Forest and Mylan, and they offer no opinions on any overarching conspiracy. Lamb Dep. 231:20-21; Elhauge Dep. 39:16-19. None of the DPPs' six other experts analyzes or opines on any reverse-payment settlement with a generic manufacturer other than Mylan, or on any purported conspiracy between Forest and the first-filing generic manufacturers.

As the Court knows, DPPs' Motion presents no claim or evidence of a conspiracy or an anticompetitive reverse payment to a generic company other than Mylan. *See* Mot. at 3 ("Forest Entered into an Illegal Reverse Payment with Mylan to Delay Generic Competition."). DPPs' own Trial Plan removes any doubt about whether DPPs are challenging the other settlements, as it only proposes to address the Forest-Mylan settlement. Litvin Decl. Ex. 2.

ARGUMENT

DPPs bear "the burden of establishing by a preponderance of the evidence that each of Rule 23's requirements has been met." *Myers v. Hertz Corp.*, 624 F.3d 537, 547 (2d Cir. 2010). In addition to establishing numerosity, commonality, typicality, and adequacy (Fed. R. Civ. P. 23(a)), DPPs also must establish that "questions of law or fact common to class members

[3] The alleged conspiring generics included Barr, Teva Pharmaceuticals USA, Inc., Cobalt, Amneal, Upsher-Smith, Wockhardt, Sun, Orchid, Dr. Reddy's, Lupin, and Mylan. Compl. ¶ 7.

predominate over any questions affecting only individual members, and that a class action is superior to other available methods" for resolving this dispute. Fed. R. Civ. P. 23(b)(3).

Courts must conduct a "rigorous analysis" and determine whether DPPs have satisfied each of these requirements through "evidentiary proof." *Comcast Corp. v. Behrend*, 133 S. Ct. 1426, 1432 (2013); *see also Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 350 (2011) (explaining that "Rule 23 does not set forth a mere pleading standard" and plaintiffs "must affirmatively demonstrate [their] compliance with the Rule"). Where such proof consists of expert opinion, the Court must "judg[e] the persuasiveness of the evidence presented," and cannot simply "end its analysis" if it finds that the evidence is admissible. *Ellis v. Costco Wholesale Corp.*, 657 F.3d 970, 982 (9th Cir. 2011). The same is true of all other relevant evidence. *In re Initial Public Offerings Sec. Litig.*, 471 F.3d 24, 42 (2d Cir. 2006). Moreover, the Court must determine whether DPPs have satisfied their burden under Rule 23, "even when that requires inquiry into the merits of the claim[s]." *Comcast*, 133 S. Ct. at 1433.

Finally, there is no merit to DPPs' suggestion that antitrust cases are especially well-suited to class certification. Although Rule 23's requirements may be "readily met in *certain cases* alleging . . . violations of the antitrust laws," *Amchem Products, Inc. v. Windsor*, 521 U.S. 591, 625 (1997), "it does not follow that a court should relax its certification analysis, or presume a requirement for certification is met, merely because a plaintiff's claims" involve antitrust violations. *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 321-22 (3d Cir. 2009). Indeed, the Supreme Court reversed class certification in an antitrust case in *Comcast*. And it has noted — in requiring antitrust class plaintiffs to proceed through individual, non-class arbitration — that Rule 23 "imposes stringent requirements for certification that in practice exclude most claims." *Am. Express Co. v. Italian Colors Rest.*, 133 S. Ct. 2304, 2309-10 (2013).

Class actions are the exception, not the rule. *Dukes*, 564 U.S. at 350.

I. DPPS CANNOT SATISFY THE REQUIREMENTS OF RULE 23(a)

A. The Proposed Class Fails the Requirement of Numerosity

To satisfy numerosity, DPPs must show that the "class is so numerous that joinder of all [class] members would be impracticable." Fed. R. Civ. P. 23(a)(1). The analysis starts with the number of proposed class members. *In re Modafinil Antitrust Litig.*, 837 F.3d 238, 250 (3d Cir. 2016). Although numerosity is presumed for classes of 40 or more members, *Consol. Rail Corp. v. Town of Hyde Park*, 47 F.3d 473, 483 (2d Cir. 1995), numerosity typically has not been satisfied for classes of 21 or fewer members. *Ansari v. N.Y.U*, 179 F.R.D. 112, 114 (S.D.N.Y. 1998). Where the class is between 21 and 40 members, "courts must consider factors other than class size." *Id.*; *In re Bayou Hedge Fund Investment Litig.*, 248 F.R.D. 404, 405 (S.D.N.Y. 2008) (McMahon, J.) ("Twenty-nine is well below the number of persons who ordinarily are certified as a class."); *see also CL-Alexanders Laing & Cruickshank v. Goldfeld*, 127 F.R.D. 454, 455-57 (S.D.N.Y. 1989) (denying certification of 25-member class). These factors include (1) judicial economy, (2) geographic dispersion, (3) the financial resources of class members, (4) their ability to sue separately, and (5) requests for injunctive relief that would involve future class members. *See Pa. Pub. Sch. Emps. Ret. Sys. v. Morgan Stanley & Co.*, 772 F.3d 111, 120 (2d Cir. 2014).

Here, after removing each of the [redacted] proposed class members that were uninjured, there are only [redacted] **potential members**.[4] *See* Lamb Rep. ¶ 42, Fig. 1. Thus, the small class size

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[redacted]

alone requires denial of DPPs' Motion. *Ansari*, 179 F.R.D. at 114. As discussed below, DPPs' Motion also should be denied because DPPs have not shown that joinder is impracticable.

1. DPPs Have Improperly Broadened the Class Definition, Intentionally Inflated the Class's Size, and Included Uninjured Class Members

DPPs have improperly attempted to expand their class by adding [redacted] "generic-only" purchasers that both lack standing and are not included in the Complaint's class definition. Moreover, DPPs have inflated the class size by including purchasers (1) that could not have been injured or (2) never bought generic IR, and (3) counting corporate family members separately.

The* [redacted] *"Generic-Only" Purchasers Must Be Excluded. Without explanation, and after fact discovery has closed, DPPs seek to greatly expand the proposed class size and potential damages. In their Complaint, DPPs sought to certify the following class:

> All persons or entities in the United States and its territories who purchased branded Namenda IR 5 or 10 mg tablets, or Namenda XR capsules, directly from Forest or its successors in interest, Actavis and Allergan, at any time during the period from September 22, 2011 until the anticompetitive effects of Defendants' conduct cease (the "Class").

Compl. ¶ 193. Now, in their Motion, DPPs have proposed a far broader class definition:

> All persons or entities in the United States and its territories who purchased branded Namenda IR 5 or 10 mg tablets, ***and/or generic Namenda IR 5 or 10 mg tablets (including an authorized generic)***, and/or branded Namenda XR capsules, directly from Forest or its successors in interest, Actavis and Allergan, ***and/or from any generic manufacturer*** at any time during the period from June 2012 until September 30, 2015 (the "Class").

Mot. at 2 (emphases added). DPPs' proposed class includes new products — generic memantine — and seeks to add purchases not only from Forest, but also "from any generic manufacturer."

[redacted]

This court should disregard the newly proposed purchasers. If DPPs intended to expand their class, they were obligated to seek leave to amend the Complaint well before fact discovery closed. DPPs cannot cure the prejudice to Forest from the deprivation of discovery on these new claims. Courts consistently refuse to consider certification of classes beyond the scope defined in the complaint absent such a non-prejudicial motion to amend. *E.g.*, *Vincent v. Money Store*, 304 F.R.D. 446, 453 (S.D.N.Y. 2015) (noting that plaintiffs may limit the class definition from the complaint, but no case permits "considerably expanding a class on a certification motion from what was originally proposed in the Complaint"); *Costelo v. Chertoff*, 258 F.R.D. 600, 604-05 (C.D. Cal. 2009) ("The Court is bound to class definitions provided in the complaint . . . .").

The reason for DPPs' amendment is transparent: without including generic-only purchasers, DPPs' proposed class falls well below the 40-member threshold for establishing numerosity. According to the data used by Dr. Lamb, redefining DPPs' class to include generic-only purchasers nearly *doubles* the number of class members. *See* Lamb Rep. Ex. 1.

DPPs' improper maneuvering should not be tolerated. Permitting DPPs to expand their class now "would of necessity totally upend the existing schedule" and "cause significant prejudice to defendants." *In re Aluminum Warehousing Antitrust Litig.*, No. 13-md-2481, 2016 U.S. Dist. LEXIS 54643, at *32-33 (S.D.N.Y. April 25, 2016) (denying motion to amend pleadings made during class certification where amendments would broaden class definition and require discovery). The time for DPPs to seek to add new class members has long passed, and DPPs do not even attempt to argue that there is good cause for doing so now. *Id.* at *27-28 (explaining that good cause requires, among other things, proof that plaintiffs were diligent but could not reasonably have modified their complaint earlier despite diligence); *Oscar v. BMW of*

N. Am., LLC, No. 09-cv-11, 2011 U.S. Dist. LEXIS 146395 (S.D.N.Y. Dec. 20, 2011) (denying motion to amend due to likelihood of additional discovery being necessary).

Moreover, it would be futile to permit DPPs to modify their class definition as the vast majority of the generic-only purchasers seek impermissible "umbrella" damages and lack standing to assert claims against Forest. Notably, unless they purchased an authorized generic, these entities could not be considered direct purchasers from Forest, because they purchased generic drugs only from unrelated generic manufacturers. *Cf. California v. ARC Am. Corp.*, 490 U.S. 93, 96 (1989) (noting that "direct purchasers" only have standing to bring federal antitrust damages claims where they purchased "directly from the . . . defendants"). With the apparent abandonment of DPPs' conspiracy claim, any purchases from a generic manufacturer (other than Mylan or Forest itself) could not form the basis of an antitrust claim. *In re Skelaxin (Metaxalone) Antitrust Litig.*, No. 1:12-md-2343, 2014 U.S. Dist. LEXIS 66707, at *29-41 (E.D. Tenn. May 15, 2014) (excluding generic overcharge damages because plaintiffs purchased the drugs from entities not part of the illegal scheme, and permitting such "umbrella" damages would conflict with *Illinois Brick Co. v. Illinois*, 431 U.S. 20 (1977), and *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519 (1983)).

Once these entities are removed, there are only [redacted] potential class members.

[redacted] ***Entities That Suffered No Injury Should Be Excluded.*** [redacted] entities — [redacted] — never bought Namenda IR and stopped buying XR before the February 2014 announcement. Hamburger Decl. Ex. 13 ¶¶ 64, 75 (Expert Rep. of Pierre-Yves Cremieux (Oct. 9, 2017)) ("Cremieux Rep."). As such, these companies could not have been injured and should not be in the class. *Id.* Another entity, [redacted] could not have been injured

because it did not make any purchases of Namenda IR or Namenda XR until after generic entry. Cremieux Rep. ¶¶ 21, 64, 75. Removing these entities leaves 29 class members.

Six Entities That Did Not Purchase Generic Memantine After It Entered the Market Should Be Excluded. [redacted] never purchased generic memantine. Cremieux Rep. ¶¶ 81, 107. As such, there is no basis to assume that these six brand-only purchasers would have purchased generic Namenda IR in the but-for world, and determination of any alleged injury to them would require individualized inquiry establishing whether they would have purchased generic memantine in the but-for world. Cremieux Rep. ¶ 108. For this reason, courts in similar cases have excluded from the proposed class members that did not make real-world generic purchases. *See, e.g.*, *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 220 n.13 (3d Cir. 2012); *In re Wellbutrin XL Antitrust Litig.*, No. 08-2431, 2011 WL 3563385, at *11 n. 2, *39-41 (E.D. Pa. Aug. 11, 2011).

Removing the four entities in this group that were not already excluded — [redacted] — leaves 25 potential class members.

Five Entities that Could Not Have Been Injured by the Product Hop Should Be Excluded. [redacted] stopped purchasing Namenda XR before the February 2014 announcement, while [redacted] never purchased Namenda XR at all. As such, they could not have been injured by the hard switch. Cremieux Rep. ¶ 75 & Ex. 1.1.

Removing the two of these entities that were not already excluded — [redacted] — leaves just 23 potential class members with respect to the product hop claim.

DPPs Double-Count Seven Class Members by Treating Corporate Family Members Separately in Their Numerosity Analysis. Purported class members that are part of the same

corporate family as other class members should not be counted separately for the numerosity analysis, otherwise the class size will be artificially inflated. *See In re Nexium (Esomeprazole) Antitrust Litig.,* 296 F.R.D. 47, 51 (D. Mass. 2013) (consolidating subsidiaries with their parents for numerosity analysis). Seven proposed class members are owned by other potential members: Bellco Drug is owned by AmerisourceBergen; Burlington Drug is owned by Smith Drug; DIK Drug, First Veterinary Supply, and The Harvard Drug Group are owned by Cardinal; and Valley Wholesale Drug and H.D. Smith Wholesale are owned by H.D. Smith LLC. Cremieux Rep. App. D. DPPs never show why these entities should be counted separately, and there is no doubt that members of the same corporate family would sue together for what DPPs characterize to be anticompetitive conduct causing the same injury. At the very least, joinder of these entities is not impracticable and they should not be counted separately. *Nexium*, 296 F.R.D. at 51.

Removing the four entities that were not already excluded — [redacted] — as well as the fifth entity that had not been excluded with respect to the reverse payment claims ([redacted]), leaves just 20 potential class members for the reverse payment claim, and only 19 for the product hop claim.

2. Joinder Is Practicable Given the Small Size of the Proposed Class and Financial Incentives of Individual Companies

This Court's "inquiry into impracticability should be particularly rigorous when the putative class consists of fewer than forty members," and should focus on "the ability of individual class members to pursue their cases through the use of joinder." *Modafinil*, 837 F.3d at 249-50. DPPs contend that the focus should be on practicality of separate actions (Mot. at 12), but Rule 23(a)(1)'s language directs courts to assess whether "the class is so numerous that *joinder* of all members is impracticable." Fed. R. Civ. P. 23(a)(1) (emphasis added). Thus,

courts in this district analyze whether joinder would be impracticable. *Deen v. New Sch. Univ.*, No. 05-cv-7174, 2008 U.S. Dist. LEXIS 7846, at *8 (S.D.N.Y. Feb. 4, 2008) ("Plaintiffs provide no evidence that joinder . . . into a consolidated action would be difficult . . . [or] somehow less efficient than class certification . . . ."); *see also Abu Dhabi Commercial Bank v. Morgan Stanley & Co.*, 269 F.R.D. 252, 258 (S.D.N.Y. 2010) (denying certification).

The test for determining whether certification will further judicial economy is not simply whether it is more convenient to try the case as a class action, but how difficult it would be to join all of the prospective class members. *CL-Alexanders*, 127 F.R.D. at 457. Here, there are no significant practical difficulties in joining all of the potential class members.

First, the class members are identifiable, making joinder practicable. *Bayridge Volvo Am., Inc. v. Volvo Cars of N. Am., Inc.*, Civ. No. 01-1890, 2004 U.S. Dist. LEXIS 16111, at *18 (S.D.N.Y. Aug. 16, 2004) ("Knowledge of names and existence of members has been called the 'most important' factor, precisely because it renders joinder practicable.") (citation omitted).

Second, the class members can share costs and resources to reduce burdens on individual plaintiffs. DPPs contend that the class members' interests are "aligned." Mot. at 15. If true, nothing would prevent all plaintiffs from sharing resources in a consolidated litigation, just as the named DPPs are doing now, including through joint filings, expert reports and discovery efforts. And although individual effort would be needed for issues that require individualized inquiry, which are discussed below, that would be true in a class action anyway. *See Dukes*, 564 U.S. at 367 (holding that, even in a class action, Rule 23 cannot be applied in a manner that would "'abridge, enlarge or modify any substantive right'") (quoting 28 U.S.C. § 2072(b)).

DPPs assert that the class members "have no pre-existing collaborative relationship[s]." Mot. at 11. [redacted]

[redacted]
Contradicting DPPs' contention that joinder for litigation "could raise its own antitrust issues" (Mot. at 11), [redacted]

Further, that resources have been expended, more discovery may be needed, or trial may be postponed, are not themselves sufficient to satisfy numerosity. *Modafinil*, 837 F.3d at 254.

After considering the same factors, the court in *King Drug Co. of Florence, Inc. v. Cephalon Inc.*, No. 2:06-cv-1797, 2017 U.S. Dist. LEXIS 137601 (E.D. Pa. Aug. 28, 2017) ("*Cephalon*"), recently denied certification of a 24-25 member class in a reverse payment case involving many of the same wholesalers here, because "joinder" of all class members would not be impracticable. The court determined that cost and resource sharing would lessen the burden of joining additional plaintiffs, and found that because most members had damages of more than $1 million there were sufficient incentives to join suit. *Id.* at *26-37. Even for those plaintiffs with less financial resources and lower potential recovery, the burden of litigation expenses would be reasonable given the availability of cost and resource sharing. *Id.*

None of DPPs' efforts to distinguish *Modafinil* and *Cephalon* are persuasive. Mot. at 12-13, 13 n.32. In *Lidoderm*, the court found *Modafinil* "not persuasive" because there were "far more DPP class members here than in that case (53 versus 22)." *In re Lidoderm Antitrust Litig.*, No. 14-md-02521, 2017 U.S. Dist. LEXIS 24097, at *73 (N.D. Cal. Feb. 21, 2017). But in this case there are fewer class members than in *Modafinil*. Moreover, the "names and addresses" of the potential class members here are known, and they have the financial resources and sophistication to join together or file their own actions. *See In re Bayou*, 28 F.R.D. at 405-06.

3. Each Potential Plaintiff Has the Incentive and Resources To Litigate

Each potential class member has a considerable financial stake in this dispute. [redacted] As such, DPPs are wrong that class members with "smaller claims" have no incentive to bring suit (Mot. at 10), and their argument "carries little weight" because attorneys' fees and treble damages are available. *Christiana Mortg. Corp. v. Del. Mortg. Bankers Ass'n*, 136 F.R.D. 372, 378-79 (D. Del. 1991) (denying certification of 28-member class for failing to satisfy numerosity requirement); *see also Cephalon*, 2017 U.S. Dist. LEXIS 137601, at *35-36.

This case is especially unsuited for class treatment as [redacted] As the Third Circuit noted in *Modafinil*: "Putting aside the small number of class members in this case, the judges in the majority have never seen a class action where three class members, each with billions of dollars at stake and close to 100% of the total value of class claims between them, have been allowed to sit on the sidelines as unnamed class members." 837 F.3d at 259.

DPPs' argument that joinder may be impracticable because some potential class members may fear retaliation by Forest is entirely speculative and should be disregarded. Mot. at 11-12. DPPs cite only two cases unrelated to Forest, and offer no evidence to support their speculation. *Cephalon*, 2017 U.S. Dist. LEXIS 137601, at *36-37 ("Direct Purchasers have again failed to offer any concrete evidence to support their concern about the hypothetical risk of retaliation and, as such, I do not find their unsupported concerns to be probative."); *see also Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 596 (3d Cir. 2012) ("speculation is insufficient" to show

Rule 23 factors). In any event, several class members have sought to act as class representatives in other antitrust actions, and their concerns of retaliation ring hollow. Hamburger Decl. ¶ 18.

4. Geographic Dispersion Does Not Warrant Class Treatment

Geographic dispersion *alone* does not establish that joinder is impracticable. *See, e.g.*, *Bayridge Volvo*, 2004 U.S. Dist. LEXIS 16111, at *12; *see also Abu Dhabi*, 269 F.R.D. at 258-59 (denying certification despite where over 100 globally dispersed members were identifiable); *Block v. First Blood Ass'n*, 125 F.R.D. 39, 42-43 (S.D.N.Y. 1989) (numerosity not satisfied because 57 dispersed members were identifiable and had significant stake in litigation). As this Court noted, dispersion is "of little moment" where the class members' identities are known and they have the resources and ability to bring suit. *In re Bayou*, 248 F.R.D. at 405.

Here, dispersion should have no effect on the certification decision. The named DPPs are already dispersed geographically — Spartanburg, SC and Rochester, NY — with neither of them located in the selected forum, while DPP counsel are located in New York, Pennsylvania, Louisiana and Texas. There will be no added burden in requiring additional plaintiffs to join this action, regardless of their location. Modern electronic discovery reduces the significance of dispersion, and counsel can handle any additional discovery and jointly prepare court filings.

5. DPPs Do Not Request Injunctive Relief

Finally, DPPs do not seek injunctive or other prospective relief and limit their class to purchases made prior to September 30, 2015, eliminating the possibility of future class members making joinder impracticable. As such, this factor weighs against certification. *See, e.g.*, *Ansari*, 179 F.R.D. at 116 (denying certification where the class consisted of a "finite number of people all of whom are identifiable and all of whom have been injured, if at all, in the past.").

B. RDC and Smith Drug's Claims Are Not Typical of the Other Class Members

The typicality inquiry is designed to avoid certifying class actions "if the representative's legal and factual positions are markedly different from those of other class members." *Burka v. N.Y.C. Transit Auth.*, 110 F.R.D. 595, 602 (S.D.N.Y. 1986) (internal quotation marks and citations omitted) (denying certification). [redacted]

[redacted] their injury from any anticompetitive conduct will not be the typical injury alleged by the named DPPs. *Cf. In re Graphics Processing Units Antitrust Litig.*, 253 F.R.D. 478, 489-90 (N.D. Cal. 2008) (denying certification of class where named plaintiffs and class members "came to the negotiating table in a fundamentally different position," some buying off of list prices, some leveraging their volume); *see also In re Intel Corp. Microprocessor Antitrust Litig.*, No. 05-md-1717, 2014 U.S. Dist. LEXIS 165261, at *33-34 (D. Del. Aug. 6, 2014).

Similarly, the class should not be certified if it contains the 31 generic-only purchasers because their claims are "not typical of the other class members." *Am. Sales Co. v. Pfizer, Inc.*,

No. 2:14-cv-0361, 2017 U.S. Dist. LEXIS 137222, at *34-35, 34 n.20 (E.D. Va. July 28, 2017). The same is true of all claims for "overcharges" based on purchases of generic memantine alone.

C. Rochester Drug and Smith Drug Are Not Adequate Class Representatives

Rule 23(a)(4) requires DPPs to establish by a preponderance of the evidence that "the representative parties will fairly and adequately protect the interests of the class." *Oakley v. Verizon Commc'ns, Inc.*, No. 09-cv-9175-CM, 2012 U.S. Dist. LEXIS 12975, at *29, *33 (S.D.N.Y. Feb. 1, 2012). Two aspects of the adequacy inquiry are at issue here.

First, "[a] class representative must not simply lend his name to a suit controlled entirely by the class attorney, as the class is entitled to an adequate representative, one who will check the otherwise unfettered discretion of counsel in prosecuting the suit." *In re Monster Worldwide, Inc. Sec. Litig.*, 251 F.R.D. 132, 135 (S.D.N.Y. 2008) (internal quotation marks and citation omitted) (denying certification). Thus, a class representative should be rejected where it has "so little knowledge of and involvement in the class action that [it] would be unable or unwilling to protect the interests of the class against the possibly competing interests of the attorneys." *Id.* (quoting *Baffa v. Donaldson, Lufkin & Jenrette Sec. Corp.*, 222 F.3d 52, 61 (2d Cir. 2000)).

[redacted]

[redacted]

When confronted with similar evidence, Judge Rakoff held that the named plaintiff was inadequate because its lack of "meaningful involvement in the case" showed it to be "the willing pawn of counsel." *In re Monster*, 251 F.R.D. at 135-36; *see also Griffin v. GK Intelligent Sys., Inc.*, 196 F.R.D. 298, 301-02 (S.D. Tex. 2000) (finding representatives inadequate who lent "their names . . . at the suggestion of lead counsel," took "little or no supervisory role over lead counsel," and did "not participate in litigation decisions"). The same result is warranted here.

Second, the named DPPs are inadequate because their interests conflict with those of other purported class members. *See, e.g.*, *Dewey v. Volkswagen AG*, 681 F.3d 170, 184, 187-88 (3d Cir. 2012) (reversing order certifying class settlement because the settlement preferred one set of class members — which included all named plaintiffs — over remaining class members). Due to the unusual aggregation of claims here, the class is significantly conflicted. Among other things, the 31 generic-only purchasers have a unique standing hurdle, and no interest in the product-hopping claim. *Supra* Sec. I.A.1. Further, the Big Three are subject to defenses that others arguably do not face and have no interest in defending against, including they may have benefitted from Forest's conduct because of the tendency for generic companies to bypass wholesalers and sell directly to retailers (generic bypass). *See Valley Drug Co. v. Geneva Pharms., Inc.*, 350 F.3d 1181, 1190, 1193 (11th Cir. 2003); Cremieux Rep. ¶¶ 36-42.

II. DPPS CANNOT CERTIFY A CLASS PURSUANT TO RULE 23(b)(3)

The predominance inquiry is "far more demanding" than Rule 23(a)'s commonality requirement. *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 623-24 (1997). It requires DPPs to establish through common proof that *each member of the proposed class* suffered antitrust impact from the alleged unlawful conduct. *See In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 311 (3d Cir. 2009). "In antitrust cases, impact often is critically important . . . because it is an element of the claim that may call for individual, as opposed to common, proof." *Id.*; *see also In re High-Tech Emp. Antitrust Litig.*, 289 F.R.D. 555, 566 (N.D. Cal. 2013) (noting that "at least five circuit courts . . . have held that for cases involving antitrust violations, common issues do not predominate unless the issue of impact is also susceptible to class-wide proof"); *see also Freeland v. AT&T Corp.*, 238 F.R.D. 130, 149-52 (S.D.N.Y. 2006) (denying certification in antitrust case for lack of class-wide proof establishing "injury to each individual class member").

Moreover, even if DPPs can establish class-wide impact, they also must establish that "damages are capable of measurement on a classwide basis." *Comcast*, 133 S. Ct. at 1432-35. DPPs are wrong that "individual damages inquiries pose[] no obstacle to certification" (Mot. at 23), because the need to consider such individual *damages* issues must be considered as part of the predominance analysis. *See Roach v. T.L. Cannon Corp.*, 778 F.3d 401, 408 (2d Cir. 2015).

DPPs are correct that they must prove "(1) a violation of antitrust law; (2) injury and causation; and (3) damages." Mot. at 17. DPPs contend that they can prove — through class-wide evidence — that the putative class members were injured "in the form of overcharges" that each ostensibly paid due to (1) the alleged reverse payment, and (2) the hard-switch. Mot. at 19-20. But DPPs do not offer any methodology for proving that each of the class members was in fact overcharged. Instead, Dr. Lamb simply assumes that [redacted]

[redacted] Lamb Rep. ¶ 67(d). As demonstrated below, nearly every issue in this case requires individualized inquiry. Neither of Dr. Lamb's two proposed models of impact and damages — [redacted] — is capable of establishing impact and damages on a class-wide basis. Therefore, common issues do not predominate, and the class cannot be certified.

A. DPPs Cannot Meet the Requirements Set Forth by the Supreme Court in *Comcast v. Behrend* for Certifying a Class under Rule 23(b)(3)

DPPs' proposed theory of antitrust impact is that Forest unlawfully paid Mylan to delay generic entry, then engaged in a "hard switch" by announcing the (unconsummated) discontinuation of Namenda IR, and that absent these actions "all or nearly all Class members would have paid less . . . by substituting less-expensive generic memantine for more expensive brand Namenda IR and Namenda XR and/or by paying less for the generic." Mot. at 19-20. As a result, DPPs' "proof of injury, or whether plaintiffs have been harmed, is bound up in proof of damages, or by how much plaintiffs have been harmed." *McLaughlin v. Am. Tobacco Co.*, 522 F.3d 215, 227 (2d Cir. 2008). If DPPs' models would not establish, on a class-wide basis, that each proposed class member suffered injury and damages, then common issues cannot predominate and the class must not be certified. *In re Rail Freight Fuel Surcharge Antitrust Litig.*, 725 F.3d 244, 249, 252-53 (D.C. Cir. 2013) ("Common questions of fact cannot predominate where there exists no reliable means of proving classwide injury in fact.").

"[A] model purporting to serve as evidence of damages in this class action must measure only those damages attributable to that theory" of antitrust impact accepted for class-action

treatment. *Comcast*, 133 S. Ct. at 1433. This Court must conduct a "rigorous analysis" to ensure that DPPs' model does so, "even when that requires inquiry into the merits of the claim." *Id.*

The core teaching of *Comcast* is fatal to DPPs' Motion. As discussed below, DPPs' models, like the model in *Comcast*, do not isolate injury from alleged anticompetitive conduct and remove any effects unrelated to that conduct. *Id*. at 1435.

1. Dr. Lamb's Product Hop Model Assumes, But Does Not Prove, Class-Wide Injury and Damages

DPPs have made no attempt to meet the specific requirements set by the Court for establishing injury stemming from the alleged hard switch. To sustain a claim, DPPs must show that they were injured by their memantine purchases because (1) patients "switched to Namenda XR *prior* to the entry of the injunction . . . because of the announced withdrawal of Namenda IR," and (2) DPPs paid more for "Namenda XR *after* generic entry." MTD Order at *38-39 (emphasis in original). These requirements exist because Judge Sweet's injunction "required Forest to affirmatively undo the effects of its February 2014 announcement." Estoppel Order at 16. Even the New York Attorney General notes the injunction "was effective in protecting competition in the relevant market." NYAG Settlement Agreement at 3.

Instead of attempting to meet the Court's requirements, DPPs rely on forecasts and assume harm. The critical flaws in Dr. Lamb's methodology are summarized below:

- [redacted]
- [redacted]

[redacted]

- [redacted]
- [redacted]

This is not a sound impact/damages methodology. It is a series of assumptions that cannot address how many patient switches were *caused* by the announcement and not undone by the injunction, and then for how many of those patients the DPPs bought XR after generic entry when DPPs otherwise would have purchased generic IR. An expert's assumptions, when challenged on class certification, must be tested and assessed. *See Hydrogen Peroxide*, 552 F.3d at 323 ("Weighing conflicting expert testimony at the certification stage is not only permissible, it may be integral to the rigorous analysis Rule 23 demands."). Here, Dr. Lamb's assumptions cannot withstand scrutiny, and do not serve as class-wide *proof* of harm from the hard switch.

a. Dr. Lamb Assumes That the Hard Switch Caused the Injury That He Was Required to Prove

To calculate aggregate hard switch damages, [redacted] This methodology does not establish injury or causation. [redacted]

> Q: . . . [S]o in that simple subtraction, your model *assumes* that all actual Namenda XR days of therapy above your but-for estimate consists of the anticompetitive hard switches at issue in this case?
>
> A: I think that's a fair way of characterizing it, sir.

Lamb Dep. 46:14-24 (emphasis added). Based on this admission alone, the Court must deny DPPs' Motion. Dr. Lamb's methodology simply assumes that all of the volume remaining from his subtraction resulted from Namenda XR sold to (1) patients who switched to XR before the December 2014 injunction and because of the February 2014 announcement, and who (2) stayed on XR beyond generic entry in July 2015 and did not reverse commute. The methodology does not even make a passing attempt to meet the Court's requirements.

The fundamental problem with Dr. Lamb's model was addressed in an analogous decision from the Second Circuit. In *McLaughlin*, the court held that a purported "market shift in brand preferences" following an announcement is not common evidence that the announcement *caused* the market shift: individualized proof is still needed to determine *why* purchasers made their purchases. 522 F.3d at 225 (decertifying class because plaintiffs' allegation that the "light" label on cigarettes duped them into believing the cigarettes were healthier would require inquiry into each plaintiff's reliance on the alleged misrepresentations); *see also Freeland*, 238 F.R.D. at 154-56 (denying certification in tying suit, where nearly 100% of customers purchased the tied product, because that did not establish on a class-wide basis that the consumers were unwilling purchasers of the product). This is because consumer purchases involve significant "idiosyncratic choice," and consumers "could have elected to purchase [their products] for any number of reasons." *McLaughlin*, 522 F.3d at 225. Similarly, Dr. Lamb's assumptions based on aggregate market data cannot explain shifts in sales of Namenda XR over time. An analysis of physician prescribing and patient preferences requires individualized proof.

To the extent that the Court has any doubts, Dr. Lamb himself confirmed that his methodology must fail under *Comcast*. Dr. Lamb conceded that his damages will likely include XR sales that were not tainted by any anticompetitive conduct, such as sales of XR to patients who simply preferred a once-daily formulation. *See* Lamb Dep. 56:7-21 (noting he does not assess specific patient or physician behavior). Dr. Lamb also confirmed that his methodology is unable to exclude first-time memantine patients over time. Lamb Dep. 48:8-49:3. This is critical because under the MTD Order, if a new patient began taking XR after the December 2014 injunction and then stayed on XR past generic entry, purchases of XR for that patient are not actionable. Dr. Lamb's damages, however, include all XR volume after July 2015, without regard to when patients first began taking XR. Indeed, Dr. Lamb's model will inevitably include purchases for patients who first started taking XR after July 2015, *i.e.*, when consumers could freely choose between XR, IR, and generic IR. This failure to isolate damages from anticompetitive conduct means that Dr. Lamb's model "cannot possibly establish that damages are susceptible of measurement across the entire class." *Comcast*, 133 S. Ct. at 1429, 1433.

b. NSP Data Do Not inform Physician or Patient Preferences

The NSP sales data set, while a helpful starting point, has several limitations, including the fact that it does not provide any insights on physician prescribing preferences, rationales, or patient preferences. Lamb Dep. at 43:21-44:5. Therefore, the data alone cannot answer whether an XR sale was due to the announcement, or whether there was reverse commuting to IR.

c. Dr. Lamb's [redacted] Cap on Lawful Namenda XR Adoption Is an Artificially Constructed Average That Excludes Relevant Data

In order to calculate hard switch damages, Dr. Lamb must first estimate the volume of Namenda XR sales but-for the hard switch. This is the "but-for Namenda XR DOT" (days of

therapy) portion of his damages formula. Lamb Rep. ¶ 146. A graphical representation of but-for Namenda XR DOT over the damages period appears in Figure 9 of Dr. Lamb's Amended Report. Lamb Rep. ¶ 156, Fig. 9. Dr. Lamb imposes a cap of [redacted] on Namenda XR adoption through lawful conduct, which he created by averaging a subset of Forest's *forecasts* of potential Namenda XR sales from soft switch conduct alone. Lamb Rep. ¶¶ 152-56 & tbl. 3.

Dr. Lamb's average is fundamentally flawed. Dr. Lamb picked just eight Forest forecasts to create his predicted [redacted] cap on lawful XR adoption. Lamb Dep. 115:8-20. [redacted] Lamb Rep. ¶ 152, tbl. 3; Lamb Dep. 145:16-149:7, 156:12-158:6; [redacted]

Dr. Lamb's selective use of data here is similar to his work in another case in which his damages methodology was criticized by a court that ultimately denied plaintiffs' motion for class certification. *In re Class 8 Transmission Indirect Purchaser Antitrust Litig.*, 140 F. Supp. 3d 339, 353 (D. Del. 2015). In that case, Dr. Lamb also "utilize[d] assumptions based on a modicum of data," and "Dr. Lamb's 'compartmentalized view' of damages does not comprise common proof that [Forest] overcharged the direct purchasers." *Id.* (quoting *In re Intel*, 2017 U.S. Dist. LEXIS 165261, at *52). The blind reliance on an average of forecasts also ignores events that occurred in the real world, which are discussed below in Section II.A.1.d.

[redacted] Dr. Lamb's decision to cap XR's but-for share at [redacted] ignores other forecasts and even the real-world XR adoption rates. [redacted]

[redacted]

d. Dr. Lamb's Structural Break Test Cannot Support an Assumption That Namenda XR Sales Above a Flawed Threshold Were Due to the Hard Switch

Dr. Lamb performed a regression that sought to identify a statistically significant structural break in the conversion rate to Namenda XR, and claims to have identified such a break around February 2014. Lamb Rep. ¶¶ 119-20. Dr. Lamb then concludes that the cause of the break was the February 2014 announcement, and argues that the test supports his belief that it had a market-wide effect. But Dr. Lamb explained precisely why the break provides no such support: his regression reveals nothing about the cause of a structural break, it only tests whether there was a break in the XR adoption rate. Lamb Dep. 95:22-96:19. Therefore, the presence of a break means little until a cause is identified, which Dr. Lamb has not done.

While it is true that economic models may employ assumptions, those assumptions must be tested and cannot be divorced from the real-world dynamics of an industry. *See Hydrogen Peroxide*, 552 F.3d at 323. Dr. Lamb's use of the structural break test is not methodologically sound because Dr. Lamb dismisses alternate and equally plausible causes. *Cf. West v. Prudential Sec., Inc.*, 282 F.3d 935, 939-40 (7th Cir. 2002) (reversing certification because "[b]y failing to test for and exclude other potential sources of [share] movement, [plaintiffs' expert] undercut the power of the inference that he advanced" that the movement was due to defendants' conduct).

For example, Dr. Lamb did not run his structural break test on individual class members' actual purchases, dismissing the idea as "not a meaningful exercise." Lamb Dep. 85:17-86:21. [redacted]

[redacted] This exercise reveals what most economists, including Dr. Lamb know to be true: tests using aggregated data often detect market-wide effects, or breaks, that may not be true for groups of purchasers in the market. Lamb Dep. 86:22-87:23. The only relevant issue here, of course, is what happened to the XR adoption rates of the proposed class members, and the absence of structural breaks for most of the members requires a more rigorous inquiry into actual causes.

On the latter point, Dr. Lamb simply dismissed factors that could have explained shifts in XR adoption rates. For example, XR was added to four major formularies in January 2014. *See* Lamb Dep. 169:7-16; *see also* [redacted] But Dr. Lamb either disregards these placements or attributes them to anticompetitive conduct. He claims that one plan, Optum, added XR because in October 2013 Forest informed Optum of its intent to withdraw IR. Lamb Rep. ¶ 102. Optum, however, decided to add XR by May 2013 based on pricing, not potential IR withdrawal. Fowdur Rep. ¶ 109. Dr. Lamb admits that trying to obtain formulary access is not anticompetitive. Lamb Dep. 164:7-165:14. But rather than inquiring into whether such placements were for lawful reasons, Dr. Lamb assumes that they resulted from unlawful conduct.

Dr. Lamb repeats this same mistake on numerous other issues. Dr. Lamb dismisses outright the impact of Judge Sweet's injunction and Forest's campaign to comply with it, despite the injunction ordering Forest to undo the announcement's effects and the New York Attorney General's recognition that Forest complied and restored competition. *See* Lamb Rep. ¶¶ 106-18; *see also* Fowdur Rep. ¶¶ 142-45. [redacted] Dr. Lamb's tendency to blur competitive and

anticompetitive conduct not only affects his underlying methodology, but also casts doubt about the assumptions and tests that he used to justify his theory of injury and causation.

2. Dr. Lamb's Reverse Payment Model Assumes, But Does Not Prove, Class-Wide Injury and Damages

The fundamental problems discussed above infect Dr. Lamb's reverse payment model as well, because both of his models rely on the same assumptions regarding XR's growth and total purchases of Namenda XR but-for the announcement. *See* Lamb Rep. ¶ 135. But the reverse payment model suffers from other flaws that render it incapable of proving class-wide impact.

First, his model is premised on assumptions regarding generic pricing and penetration that are untethered from the actual world and sound economic theory. For example, Dr. Lamb was instructed by DPP counsel to assume that three generic manufacturers would have immediately entered at the same time as Mylan but-for the allegedly unlawful Forest-Mylan agreement. Lamb Rep. ¶ 129. Although this assumption appears to be based on opinions offered by DPP expert Ms. DeLeon, Ms. DeLeon never opines that four generic manufacturers in fact would have entered immediately upon either a victory by Mylan in the patent litigation or a negotiated settlement with Forest that permitted entry in 2012. Cremieux Rep. ¶¶ 96-97.

Then, in calculating damages, Dr. Lamb disregards his counsel's instructions and uses ratios of *actual* generic IR penetration rates and prices, shifted back in time to his but-for generic entry dates. Oddly, Dr. Lamb departs from his own model, but the problem is that using actual generic pentration rates and prices inflates damages. For example, six generic manufacturers entered in the real world, exerting more pricing pressure than the four he presumes would enter in the but-for world would have exerted. Cremieux Rep. ¶¶ 94, 97 n.119 (noting that, according to economic literature, entry by four generics is not likely to result in as low of generic prices or

as high of a generic penetration rate as entry by a larger number of generics). Dr. Lamb thus proposes no methodology for calculating generic pricing or the generic penetration rate in the but-for world that he posits and DPPs intend to prove. *Id.*

Dr. Lamb's reliance on DPP counsel's instruction for his but-for generic entry dates also is dependent on unwarranted assumptions. For instance, Dr. Lamb relies on Professor Elhauge's assumption that Forest would have launched [redacted] which stands in stark contrast to Forest's actual launch of XR 25 months prior to generic entry, and undermines his entire methodology for assessing impact and damages. Cremieux Rep. ¶¶ 92-93. He also uncritically relies on Professor Elhauge's predicted generic entry dates of [redacted]. But as Dr. Lamb admitted, if the jury finds a different generic entry date, then he would be forced to recalculate his damages estimates. Lamb Dep. 209:2-15.

Second, Dr. Lamb takes the total amount of purported reverse-payment damages and allocates them to each proposed class member, thus assuming that each member was injured by the alleged reverse-payment and product-hop. Lamb Rep. Ex. 1. As Dr. Lamb notes, this allocation is based on *total memantine* purchases by each DPP (with brand-generic damages allocated based on total Namenda XR and IR purchases, and generic-generic damages based on total generic purchases). *See* Lamb Dep. 224:5-13. Thus, Dr. Lamb's allocation awards damages for the product hop to entities that never even purchased Namenda XR (*i.e.*, only Namenda IR) and could not have been injured by the alleged product hop. Lamb Dep. 228:4-20. He similarly allocates damages and assumes injury to entities that never purchased generic IR and thus could not have been injured by any of Forest's conduct, and to entities that could not have been injured by the alleged reverse payment to Mylan. Cremieux Rep. ¶ 108.

3. DPPs' Failure to Offer a Method Capable of Proving Class-Wide Injury and Damages Precludes Certifying Their Proposed Class

The fact that Dr. Lamb's only proposed methodology for proving class-wide impact and damages "detects injury where none could exist . . . shred[s] the plaintiffs' case for certification." *Rail Freight*, 725 F.3d at 252-53 (concluding that where a combined impact/damages model is defective, "[n]o damages model, no predominance, no class certification"). The need to engage in individualized inquiries into injury "overwhelm questions common to the class," *Comcast*, 133 S. Ct. at 1433, and thus certification should be denied.

Perhaps in recognition that they cannot establish class-wide impact, DPPs wrongly argue that "[c]lass certification is proper even if . . . this Court were to find that 'the issue of injury-in-fact presents individual questions." Mot. at 18 (citing *Cordes*, 502 F.3d at 108). Since deciding *Cordes*, "the Second Circuit has explained [that], while the need for individualized inquiry into damages does not [necessarily] defeat (b)(3) certification, plaintiffs must nevertheless 'show that they can prove, through common evidence, that all class members were . . . injured by the alleged [conduct].'" *Laumann v. NHL*, 105 F. Supp. 3d 384, 398 (S.D.N.Y. 2015) (quoting *Sykes v. Mel S. Harris & Assocs. LLC*, 780 F.3d 70, 82 (2d Cir. 2015) (citing *Rail Freight*, 725 F.3d at 252)). DPPs' inability to do so means that the class cannot be certified. *Id.*

DPPs are similarly mistaken that the Court should certify a class that "includes some uninjured members." Mot. at 18. As one of the cases they cite notes, a class definition "is too broad" to be certified where, as here, it "sweeps within it persons who could not have been injured." *Kohen v. Pac. Inv. Mgmt. Co.*, 571 F.3d 672, 677 (7th Cir. 2009). Moreover, because a class member could not bring its own claim without establishing its injury and thus its standing, this Court cannot confer on DPPs "different rights in [a] class proceeding than they could have

asserted in an individual action." *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036, 1048 (2016); *see also Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1548 (2016) (noting that, even in class actions, standing exists only for actual injuries that "affect the plaintiff in a personal . . . way").

B. DPPs' Overarching Theory of Damages Is Inapplicable to Namenda XR Purchasers — The Proper Measure of Damages is Lost Profits

Damages in antitrust cases typically take one of two forms: "(1) overcharges paid for goods actually purchased; and (2) lost profits resulting from the lost opportunity to buy and resell a greater volume of goods." *Howard Hess Dental Labs. Inc. v. Dentsply Int'l, Inc.*, 424 F.3d 363, 373-74 (3d Cir. 2005). Contrary to DPPs' assertion, this Court did not hold that overcharges are the appropriate measure of harm in this case. Mot. at 19. Rather, Judge Francis noted that some cases have held that overcharges are the proper measure of harm in similar actions, but "[u]ltimately" held that Forest did not need the discovery it sought to measure lost profits because DPPs said "that they will not seek to prove that they have lost profits" and "'do not claim to have lost profits.'" *In re Namenda Direct Purchaser Antitrust Litig.*, No. 15-cv-7488, 2017 U.S. Dist. LEXIS 95796, at *20-21 (S.D.N.Y. June 21, 2017). He then left the issue for this Court to resolve: "if Judge McMahon were ultimately to decide that lost profits are the proper measure of damages, the plaintiffs could not recover on the Section 2 claim." *Id.*

Where injury allegedly stems from purchasing a brand drug and its AB-rated equivalent, measuring the difference in price between the two may be an appropriate means of proving damages because the two drugs are effectively the same product. *In re Terazosin Hydrochloride Antitrust Litig.*, 203 F.R.D. 551, 557-58 (S.D. Fla. 2001). Throughout this case, however, DPPs have maintained that Namenda XR and generic memantine are not the same products, and even now DPPs do not opine that XR purchases would be directly replaced by generic memantine,

because the two drugs are not AB-rated to each other. Cremieux Rep. ¶ 49. Instead, DPPs contend that Forest made generic memantine unavailable to them, which is the same argument raised in antitrust actions based on a refusal to sell. In such cases, the accepted measure of damages is lost profits. *See Bigelow v. RKO Radio Pictures, Inc.*, 327 U.S. 251 (1946); *see also* Cremieux Rep. ¶¶ 37-39 (explaining that lost profits is the only proper measure of damages).

Where lost profits are at issue, courts often refuse to certify classes because individual issues unique to the class members' profits are likely to dominate the proceedings. *See, e.g.*, *Broussard v. Meineke Discount Muffler Shops, Inc.*, 155 F.3d 331, 342-43 (4th Cir. 1998); *Bell Atl. Corp. v. AT&T Corp.*, 339 F.3d 294, 306 (5th Cir. 2003). Regardless, because DPPs do not contend that they lost profits due to Forest's conduct, DPPs cannot offer class-wide proof of their injury or damages using the proper measure of economic harm in this type of case. Accordingly, DPPs have no means of complying with Rule 23(b)(3) and their Motion should be denied.

CONCLUSION

For the foregoing reasons, this Court should deny DPPs' Motion for Class Certification.

Dated: October 9, 2017

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CERTIFICATE OF SERVICE

I hereby certify that on October 9, 2017, true and correct copies of the following were filed via the Court's CM/ECF system, and confidential versions of the below materials were served upon all parties via electronic mail:

- Forest's Opposition to Direct Purchaser Plaintiffs' Motion for Class Certification;
- Declaration of Michael E. Hamburger in Support of Forest's Opposition to Direct Purchaser Plaintiffs' Motion for Class Certification, and accompanying exhibits.

Dated: October 9, 2017
New York, NY

Respectfully submitted,

/s/ *Michael E. Hamburger*

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